K034035

MAR 2 4 2004

IMPLANT INNOVATIONS, INC.
A BIOMET COMPANY

Summary of Safety & Effectiveness

COMPANY:	Implant Innovations, Inc. 4555 Riverside Drive Palm Beach Gardens, FL 33410
CONTACT:	Jim Banic Regulatory Affairs Specialist Telephone: 561-776-6932 Fax: 561-514-6316 E-mail: jdailey@*3i*mplant.com
DATE PREPARED:	December 26, 2003
NAME OF THE DEVICE:	*3i* Patient-Specific Overdenture Bar
CLASSIFICATION:	DZE Class III
COMMON NAME:	Overdenture Bar
PREDICATE DEVICES:	The *3i* Patient-Specific Overdenture Bars are substantially equivalent to overdenture bars, (commonly referred to as Hader, Dolder, and Primary) currently on the market in overall design and intended use. Overdenture bars have been in existence for more than thirty years and have been traditionally fabricated in individual dental laboratories. Predicate device includes: K974150 Nobel Biocare, Inc. Procera® Preparable Abutment System

DEVICE DESCRIPTION:	The *3i* Patient-Specific Overdenture Bars are designed to match individual patients.
INDICATIONS FOR USE:	The *3i* Patient-Specific Overdenture Bars are intended for use as an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support multiple tooth prostheses, in the mandible or maxilla. The prostheses are screw retained to the abutment.
SUMMARY OF SAFETY AND EFFECTIVENESS:	Safety and effectiveness problems that have been encountered with overdenture bars used with endosseous implants may include occasional fractures of the screw; screws becoming loose; or improper mating resulting in inflammation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2004

Mr. Jim Banic
Regulatory Affairs Specialist
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K034035
Trade/Device Name: 3i Patient-Specific Overdenture Bars
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA
Dated: December 26, 2003
Received: December 29, 2003

Dear Mr. Banic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

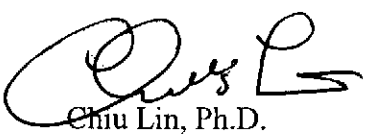
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K034035

Device Name: 3i Patient-Specific Overdenture Bars

Indications for Use:

The 3i Patient-Specific Overdenture Bars are intended for use as an accessory to an endosseous dental implant to support a prosthetic device in an edentulous or partially edentulous patient. It is intended for use to support multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be screwed retained.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K034035